

ABSTRACT

A method of sterilizing a medical device component, such as a catheter balloon, in which an electron beam (i.e., e-beam) is applied to the component in an evacuated or inert gas-filled container. The method of the invention allows for electron beam sterilization without significant degradation of the component polymeric material. In one embodiment, the device component is configured to be pressurized or expanded during use. The method of the invention provides a component with a rupture pressure that is not significantly decreased due to electron beam sterilization. Another aspect of the invention is a medical device component, e-beam sterilized according to a method of the invention. A variety of medical device components can be sterilized by the method of the invention, and particularly intracorporeal devices for therapeutic or diagnostic purposes, such as balloon catheters, catheter shafts and balloons, stent covers, and vascular grafts.

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